COALITION OF

Wound Care Manufacturers

July 24, 2015

Dr. Antonietta Sculimbrene
Medical Director
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Part B Policy
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Columbia, SC 29202-3238

Submitted electronically to: J11B.Policy@PalmettoGBA.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds (DL36123

Dear Dr. Sculimbrene:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to be submitting our comments to Palmetto on its draft local coverage determination for Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds ((DL36123)**.** The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to provisions contained in this Guidance. As such we have a particular interest in this draft document. For your reference, throughout our comments, we refer to "Skin Substitutes" as Cellular and/or Tissue Based Products for Wounds (CTPs) as it is a more clinically appropriate term and has widely been accepted in the clinical community when referring to these types of products.

Skin Substitutes is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace for products that contain living cells or constitute tissue-based products intended for use in the management, treatment, or healing of skin wounds. Historically, these products have been referred to as "skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedures. However, over time, the usage of these products shifted toward chronic ulcers where skin grafts are infrequently used and not standard of care. Moreover, newer products in this category may look nothing like skin and, indeed, have not been designed to function as skin replacements. Thus, there is a need to define terminology in the context of skin wounds as opposed to skin grafting procedures.

As such, the Coalition recommends that Palmetto adopt the term "Cellular and/or tissue

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based products for wounds**"** ("CTPs") which does accurately describe and is broad and inclusive of both current and future technology. We would respectfully point out that other organizations, contractors, and the wound care clinical community are adopting this verbiage. For instance, American Society of Testing and Materials (ASTM) has created a new draft guidance standard specifically using the CTP nomenclature. In addition, Cigna Government Services is utilizing the term "Cellular and/or Tissue Based Products for Wounds" as the title for its LCD.

Our specific comments follow.

Clinical Evidence

As manufacturers, Coalition members have and will continue to support evidence based medicine as well as the investigation of our technologies including but not limited to randomized controlled trials, case studies and white papers. However, it is difficult to support a policy in which we do not know what evidence will be required in order to gain and/or maintain coverage. It is unclear how Palmetto will judge the supportive clinical evidence for each product used. As such, the Coalition highly recommends that Palmetto clearly identify what evidence they are seeking and if a product meets those criteria – then it would be covered.

The Coalition believes that evidence can be established for coverage not only through RCTs but also through Registry data, retrospective clinical studies (which includes populations of patients with multiple comorbid conditions that are commonly eliminated in most RCTs), scientific evidence and expert knowledge. This approach is consistent with the widely accepted definition of evidence-based medicine but also adopted by the newly created important organization Patient Centered Outcomes Research Institute (PCORI). **We believe that payers should cover these CTPs if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products without regard of how they are regulated by the FDA—Class II, III or HCT/Ps nor how they compare to other products in the marketplace**.

Finally, to continue to ensure a transparent process in place, the Coalition urges Palmetto to have a process in place prior to any making any changes to the coverage policy based on evidence presented to Palmetto which could impact a products coverage status.

Inconsistencies and Inaccuracies Within the Draft

While the Coalition commends Palmetto in their decision to allow for these products to be covered based on the clinical decision making process of the clinician treating a patient with a chronic non-healing wound, the draft is at times confusing and contains inconsistent and inaccurate language. The Coalition is a non-clinical, non-voting member of the Alliance of Wound Care Stakeholders (Alliance). We are aware that the Alliance

submitted comments on the clinical inconsistencies and inaccuracies in this draft policy. We support their comments and request that Palmetto implement their recommendations prior to this policy becoming final.

Conclusion

We appreciate the opportunity to provide you with our comments on this important draft policy. Should you have any questions or require any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

Karen S. Ravitz, JD
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